IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

DOUGLAS KAYE	§	
	§	
Plaintiff	§	
	§	
VS.	§	**CAUSE NO. 4:05-CV-02809**
	§	
SYNTHES (U.S.A.)	§	
	§	
Defendant	§	

AFFIDAVIT OF MARC R. LABBE´

STATE OF TEXAS §
§
COUNTY OF HARRIS §

BEFORE ME, the undersigned authority on this date personally appeared, Marc R. Labbe´, M.D., known to me to be the person whose name is subscribed to the following instrument, and having been by me duly sworn, upon his oath deposes and states as follows:

1. "My name is Marc R. Labbe´, M.D. I am over 18 years of age, and am otherwise competent to make this Affidavit. I have personal knowledge of the facts stated herein and they are true and correct.

2. "I am a Board Certified Orthopedic Surgeon that has been practicing orthopedic surgery for the past 3 years. I am currently the Clinical Assistant Professor of the Department of Orthopedic Surgery at Baylor College of Medicine. In addition, I am fellowship trained in sports medicine, which involves care of shoulder, knee and elbow injuries. I have been directly involved in the surgical treatment of fractures, including clavicle fractures since the beginning of my training in 1997. A true and correct copy of my Curriculum Vitae is attached hereto as Exhibit A.

3. "I have reviewed Douglas Kaye's medical records from Sweetwater Radiology Associates, Houston Orthopedic Medicine, Southwest Bone and Joint Clinic, Fletcher Allen Health Care, Sugar Land

Surgical Hospital and the deposition of the treating physician, Dr. Timothy Sitter. These records reflect Mr. Kaye's surgical care and treatment following his March 3, 2003, skiing accident resulting in multiple injuries, including a clavicular fracture. Based on this review as well as my skill and training as an orthopedic surgeon, I have formulated certain opinions which are set out herein. These opinions are based on a reasonable degree of medical probability. I authored a report dated July 20, 2006, reflecting my opinions in this matter. A true and correct copy of my report is attached as Exhibit B.

4. "As a part of my orthopedic practice, I am skilled, trained, and knowledgeable in the use of a variety of fracture fixation devices including plates and screws. Specifically, I have personal knowledge in the proper choice and use of the Synthes line of plates and screws, including the 1/3 semitubular plate with collar, which is the plate chosen by Dr. Sitter in his June 23, 2003 revision surgery. I have personally used this plate extensively and continue to use it. I would not do so if I had any doubt about this plate's design or manufacture. This plate – Synthes' 1/3 semitubular plate with collar – was in 2003 and remains today an appropriate choice for many patients, depending upon the particular patient's condition and circumstances.

5. "I am also familiar with the Synthes generic package inserts which accompany its plates such as the 1/3 semitubular plate with collar. I find this package insert to be appropriate and consistent with the practices and general knowledge that a well trained orthopedic surgeon should have. A copy of the generic insert which would have been included in the shipment of the subject 1/3 semitubular plate with collar is attached hereto as Exhibit C. All of the medical information contained in this insert is learned during an orthopedic surgeon's training and is common knowledge within the community of orthopedic surgeons. I believe this insert is both sufficient and appropriate.

6. "In conjunction with my medical practice, I have personal experience in the design of surgical equipment. I am also familiar with elements of the design of Synthes' 1/3 semitubular plate with collar, and have formulated opinions about this plate's design. Specifically, I have no doubt as to the adequacy of the plate's design and feel that it is an appropriate plate to use for fracture fixation in the right setting.

7. "I have encountered situations where plates have broken and/or screws have backed out. Such occurrences are not very common but are a well-recognized possible complication associated with the use of fracture fixation devices. Any reasonably trained orthopedic

surgeon should be well aware of this possibility and understand many of the circumstances surrounding plate breakage. The most common cause of plate breakage is fatigue fracture. Fatigue fracture occurs as the plate is repetitively bent or undergoing repeated loading over time. Typically, plates are fractured in the area of screw holes, as it is the weakest portion of the plate. In this case, I saw no indication that the Synthes plate was defective or otherwise unfit for the ordinary purpose for which such plates are used and the bare fact that a plate broke does not necessarily mean that the plate was defective or otherwise unfit for the purpose for which these plates are intended. It is my opinion that the subject plate breakage was due to fatigue and not due to any design defect. Shortly after the second surgery during which the Synthes 1/3 semitubular plate with collar was applied, Mr. Kaye resumed his activities as a scissor sharpener and other activities, including moving a refrigerator. These activities can place significant loads on the clavicle and, in this case, the plate.

8. "In my review of Mr. Kaye's case, I have seen nothing to indicate or in any way raise a suspicion of a defect in the Synthes 1/3 semitubular plate with collar. Certainly, the fact that the plate broke, is not in and of itself, an indication of a product defect. The fact of the matter is plates can, and occasionally do, break without being in any way defective. I believe that is what happened in this case. As a result, any medical expenses or other related damages experienced by Mr. Kaye following the breakage of the Synthes 1/3 semitubular plate with collar used as part of his second surgical fixation, flow from and were caused by his skiing accident on March 3, 2003.

"Further affiant sayeth not."

Signed this 20th day of October, 2006.

Marc R. Labbé, M.D.

SUBSCRIBED AND SWORN TO BEFORE ME on this the 20 day of October 2006, to certify which witness my hand and seal of office.

JOAN B. GILES
Notary Public, State of Texas
My Commission Expires
June 23, 2010

Notary Public in and for the State of Texas
My Commission Expires: 06/23/2010

Curriculum Vitae

MARC R. LABBÉ, M.D.

Date of Birth: 6 July 1971

Place of Birth: Calgary, Alberta Canada

Home Address:
3424 Sunset Blvd.
Houston, Texas 77005
Phone: (713) 592-6640
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Office Address:
6624 Fannin Street, Suite 2600
Houston, Texas 77030
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Education:

College: The Johns Hopkins University 1989-1993
Baltimore, Maryland
Bachelor of Arts in Biology
Minor in Psychology

Medical School: Baylor College of Medicine 1993-1997
Houston, Texas
M.D. Degree

Postgraduate Training:

Residency: Baylor College of Medicine 1997-2002
Houston, Texas
Department of Orthopedic Surgery

Fellowship: Mississippi Sports Medicine and Orthopaedic Center 7/02-8/03
Sports Medicine and Arthroscopy Fellowship

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Board Certification:

Board Certified, 2005
American Board of Orthopedic Surgery

Practice Experience:

Bone and Joint Clinic of Houston, P.A.
Houston, Texas 77030 8/2003-present

Hospital Appointments:

St. Luke's Episcopal Hospital
Houston, Texas 77030 8/2003-present

V. A. Medical Center
Houston, Texas 77030 8/2003-present

Academic Appointments:

Clinical Assistant Professor 8/2003-present
Department of Orthopedic Surgery
Baylor College of Medicine
Houston, Texas 77030

Professional Associations:

American Academy of Orthopaedic Surgeons
American Medical Association
American Orthopaedic Society for Sports Medicine
Arthroscopy Association of North America
Harris County Medical Society
Mississippi Orthopaedic Society

Presentations:

The Short-term Efficacy of Hyaluronic Acid Injections for Degenerative Arthritis of the Shoulder. Presented to the Arthroscopy Association of North American, April 2003.

Publications:

1. Labbé, Arthroscopic Technique for Patch Augmentation of Rotator Cuff Repairs, ***Arthroscopy***, Accepted for publication on 3/9/06 – no printing date given

Publications, cont'd...

2. Labbé, M., Savoie III, F.H., Overuse Injuries Elbow Injuries. ***OKU 3 Sports Medicine***, Garrick, J. ed., AAOS 2004, 91-100.

3. Labbé, M., Field, L. The Role of Thermal Surgery in the Throwing Athlete. ***Sports Medicine and Arthroscopy Review***, June 2004, 12(2), 135-138.

4. Ilahi, O.A., Younas, S.A., Labbé, M.R., Edson, S.B. The prevalence of ganglion cysts originating from the proximal tibiofibular joint: A magnetic resonance imaging study. ***Arthroscopy***, Feb. 2003, 19:2, 150-153.

5. Ilahi, O.A., Labbé, M.R., Cosculluela, P. Variants of the Anteriosuperior glenoid labrum and associated pathology. ***Arthroscopy***, Oct. 202, 18:8, 882-886.

6. Joshi, A., Labbé, M., Lindsey, R., Humeral fracture secondary to civilian gunshot injury. ***Injury***, 1998, Suppl. 1:SA1 3-7.

Teaching Activities:

Instructor, American Academy of Orthopedic Surgeons Shoulder Arthroscopy Course, Chicago, Illinois, April 2003, February 2006.

Faculty Member and Guest Lecturer, Chilean Orthopaedic and Traumatology Society Meeting, Vina del Mar, 2004

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Walter R. Sassard, M.D.
Todd E. Siff, M.D.
Marc R. Labbé, M.D.
Frank T. Gerow, M.D.

July 20, 2006

Mrs. Deanna H. Livingston
Livingston & Livingston
1770 St. James Place, Suite #100
Houston, TX 77056-3405

RE: ***Cause No. 4:05-CV-02809; Douglas Kaye v. Synthes (U.S.A.)***

Dear Ms. Livingston:

I am a Board Certified Orthopedic Surgeon. As you can see from my Curriculum Vitae, I have practiced orthopedic surgery for three years. Currently, I hold a position as Clinical Assistant Professor in the Department of Orthopedic Surgery at Baylor College of Medicine. I am fellowship trained in sports medicine, which involves care of shoulder, knee and elbow injuries. I have been directly involved in the surgical treatment of fractures, including clavicle fractures since the beginning of my training in 1997.

I have reviewed the medical records regarding Douglas Kaye from Sweetwater Radiology Associates, Southwest Bone and Joint Clinic, Fletcher Allen Health Care, Sugar Land Surgical Hospital and a written version of the deposition of Dr. Timothy Sitter.

My review of the records shows that Mr. Kaye was involved in a skiing accident, which resulted in multiple injuries, including a clavicular fracture. He was evaluated by Dr. Hicks, who recommended non-surgical treatment, and then by Dr. Sitter, who performed his subsequent 4 procedures. He underwent an initial open reduction and internal fixation with a Smith & Nephew plate & screws. The patient later complained of pain over the plate and that a prominence developed over the clavicle and elected to undergo a second procedure, which involved removal of the initial plate, an osteotomy to realign the bone, and fixation with Synthes 1/3 semitubular plate with collar, the plate of which is the basis of this litigation. Approximately five weeks after his second surgery, his plate was found to have been broken, and the patient underwent a third procedure with removal of the 1/3 semitubular plate with collar and placement of Synthes, LC-DCP plate and screws. The fracture then healed, and the LC-DCP plate was removed at the patient's request in a fourth procedure.

As a part of my orthopedic practice, I am skilled, trained, and knowledgeable in the use of a variety of fracture fixation devices including plates and screws. Specifically, I have personal knowledge in the proper choice and use of the Synthes line of plates and screws, including the 1/3 semitubular plate with collar. I have personally used this plate extensively and continue to use it. I am also familiar with the accompanying package inserts and find them to be appropriate and consistent with the practices and general knowledge that a well trained orthopedic surgeon should have. I have no doubt as to adequacy of

EXHIBIT
B

the plate's design and feel that it is an appropriate plate to use for fracture fixation in the right setting. I do have personal experience in the design of surgical equipment.

I have encountered situations where plates have broken and/or screws have backed out. Such occurrences are not very common but are a well-recognized possible complication. Any reasonably trained orthopedic surgeon should be well aware of this possibility and understand many of the circumstances surrounding plate breakage. The most common cause of plate breakage is fatigue fracture. Fatigue fracture occurs as the plate is repetitively bent or undergoing repeated loading over time. Typically, plates are fractured in the area of screw holes, as this is the weakest portion of the plate. It is my opinion that the plate fracture is due to fatigue and not due to design defect. Shortly after the second surgery during which the plate was applied, the patient was resuming his activities as a scissor sharpener and other activities, including moving a refrigerator. These activities can place significant loads on the clavicle and, in this patient's case, the plate.

Sincerely,

Marc R. Labbé, M.D.

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

SUGGESTIONS CONCERNING ORTHOPAEDIC METALLIC INTERNAL FIXATION DEVICES

SYNTHES®

3/02 GP0030-H

The use of metallic surgical implants has given the surgeon a means of bone fixation and helps generally in the management of fracture and reconstructive surgery; however, these implants are intended only to assist healing and not intended to replace normal body structures. Metallic bone fixation devices are internal splints which align the fracture while normal healing occurs. The size and shape of bones and soft tissue place limitations on the size and strength of implants. If there is delayed union or nonunion of bone in the presence of weight-bearing or load-bearing, the implant could eventually break due to metal fatigue. Therefore, it is important that immobilization of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. All metallic surgical implants are subject to repeated stresses in use, even in the absence of direct weight-bearing, which can result in metal fatigue. Factors such as the patient's weight, activity level, and adherence to weight-bearing or load-bearing instructions have an effect on the stresses to which the implant is subjected, and therefore on the life of the implant.

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant but also must be aware of the mechanical and metallurgical aspects of surgical implants. Postoperative care is extremely important. The patient must be warned that non-compliance with postoperative instructions could lead to loosening or breakage of the implant, and/or possibly migration, requiring revisional surgery.

The following are specific warnings, precautions, and adverse effects which must be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

Warnings

1. **Correct selection of the implant is extremely important.** The potential for success of fracture fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand activity levels and/or loads equal to those placed on normal healthy bone as **these devices are not designed to withstand the unsupported stress of full weight-bearing or load-bearing*.**
2. **These devices can break when subjected to the increased loading associated with delayed union or nonunion*.** Internal fixation appliances are load-sharing devices which hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight-bearing and activity levels will dictate the longevity of the implant. The patient should understand that stress on an implant can involve more than weight-bearing. In the absence of solid bony union, the weight of the limb alone, muscular forces associated with moving a limb, or repeated stresses of apparent relatively small magnitude, can result in failure of the implant. Notches or scratches put in the implant during the course of surgery may also contribute to breakage.
3. **Corrosion.** Implanting metals and alloys in the human body subjects them to an aggressive chemical environment of salts, acids, and proteins, which can cause corrosion. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Thus, mixing of implant components from different manufacturers is not recommended, for metallurgical, mechanical and functional reasons.
4. Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

**Vertebral body replacement devices (regardless of the indication for which they are designated) are designed to withstand both full load-bearing and the loads associated with long-term use which could result from the presence of non-union or delayed union. To ensure load-bearing ability and the loads associated with long-term use, supplemental fixation is required with the use of this device. Please refer to the product specific insert for these types of device systems for additional information, (i.e., descriptions, indications, etc.).*

Precautions

1. **Surgical implants must never be reused.** An explanted metal implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.
2. **Correct handling of the implant is extremely important.** Contouring of metallic implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.
3. **Removal after fracture healing.** Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management to avoid refracture. *Note: Only the supplemental fixation component of a vertebral body replacement system should be removed after treatment of a vertebral body fracture and identification of the presence of fusion.*
4. **Adequately instruct the patient.** Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful fracture healing. This is particularly important should the device be used to treat an unstable fracture, such as intertrochanteric or subtrochanteric. The patient must be made aware of the limitations of the implant and that physical activity and full weight-bearing or load-bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under normal weight-bearing or load-bearing in the absence of complete bone healing. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Possible Adverse Effects

1. Nonunion or delayed union which can lead to breakage of the implant.
2. Metal sensitivity, or allergic reaction to a foreign body.
3. Limb shortening due to compression of the fracture or bone resorption.
4. Decrease in bone density.
5. Pain, discomfort, or abnormal sensations due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of bone.
8. Vascular changes.

Sterility

Unless supplied sterile, metallic internal fixation devices must be sterilized prior to surgical use. Steam sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline "Good Hospital Practice: Steam Sterilization and Sterility Assurance." The cycle parameters recommended in this standard are suggestions. It is the user's responsibility to validate any steam sterilization parameters that are not provided directly by the manufacturer.

Implant Usage

The use of AO surgical implants has given the surgeon a means of stable internal fixation in the management of fractures and reconstructive surgery. However, the surgeon should be fully aware that AO implants are intended for use in internal fixation in accordance with techniques developed by the AO group. The products should not be used unless the surgeon is thoroughly familiar with the AO method as described in the latest editions of the *Manual of Internal Fixation by M.E. Müller, et. al (Publisher Springer-Verlag. New York, Heidelberg, Berlin), AO Principles of Fracture Management, by T.P. Rüedi and W.M. Murphy (Publisher Thieme. Stuttgart, New York), Manual of Internal Fixation in the Cranio-Facial Skeleton by L.A. Assael, et. al (Publisher Springer-Verlag. New York, Heidelberg, Berlin), and the Small Fragment Set Manual by U. Helm and K. M. Pfeifer (publisher Springer-Verlag. New York, Heidelberg, Berlin).* It is also recommended that surgeons utilizing these instruments and implants attend one of the various AO/ASIF instructional courses offered periodically in North America and around the world.

Additional information regarding specific devices may be obtained from Synthes.

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